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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,959	06/25/2001	Richard Ian Christopherson	DAVII39.001CI	2583

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/888,959	CHRISTOPHERSON ET AL.
Examiner	Art Unit	
Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Nov. 6, 2002 .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 25 June 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____ .

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .

4) Interview Summary (PTO-413) Paper No(s) _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species of chronic lymphocyte leukemia in Paper No. 5, filed Nov. 6, 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-17 are pending.

Claims 8-17, drawn to non-elected species, are withdrawn from consideration.

Claims 1-7 are examined on the merits.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant's attention is drawn to pages 3, 50 and 55 where embedded hyperlinks were found. Applicant is advised to carefully review the specification for other instances of embedded hyperlinks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by either Robbins (Robbins, B.A. et al., Blood, 82(4): 1277-1287, 1993) or Valet (Valet, G.K. et al, Cytometry, 20: 275-288, 1997).

In view of the election of species requirement, claims 1-7 are interpreted as drawn to methods for identifying a type of leukemia comprising contacting a sample with an array of immunoglobulin molecules that interact with CD antigens, wherein at least one of the immunoglobulin molecules in the array is capable of interacting with a CD antigen from chronic lymphocytic leukemia (CLL).

Robbins teaches a method of contacting samples with pairs of antibodies that are specific for CD antigens (see Table 2, page 1278). CD antigens such as CD19 and CD5 are specific for CLL. Robbins teaches methods that are within the scope of claim 4, because Robbins teaches a method using the pair CD3 and CD19. Robbins teaches methods that are within the scope of claim 5, because Robbins teaches a method using the pair CD4 and CD8. Robbins teaches methods that are within the scope of claim 6, because Robbins teaches a method using pair CD19 and CD25. Robbins teaches methods that allow one to distinguish HCL from CLL (see abstract). Valet teaches methods of contacting samples with three antibodies that bind to CD antigens (CD4, CD8, and CD3, or CD45, CD14, and CD20 or CD10, CD23 and CD19). Valet

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teaches methods that are within the scope of claims 4 or 5, because Valet teaches methods using CD3, CD4 and CD8. Valet teaches methods that are within the scope of claim 6, because Valet teaches methods using antibodies that bind CD10, CD19 and CD23. Thus, either Robbins or Valet teaches methods that are the same as that claimed.

4. Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Terstappen (U.S. Patent 5,234,816; issued August, 1993).

Terstappen discloses methods for classifying leukemias comprising contacting samples with antibodies that bind to CD antigens (see, for example, col. 2, line 66 – col. 3, line 25). Thus, Terstappen discloses methods that are the same as that claimed.

5. Claims 1-3, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Moreau (Moreau, E.J. et al, Am. J. Clin. Pathol., 108: 378-382, 1997), Matutes (Matutes, E. et al., Blood, 83(6):1558-1562, 1994) or Kurec (Kurec, A.S. et al, British J. Haematology, 81: 45-51, 1992).

Moreau teaches a method for diagnosing CLL based on a binding pattern to a panel of antibodies that bind to CD antigens that include CD antigens of CLL cells (see page 380, Tables 3-5). Matutes teaches a method to distinguish splenic lymphoma with villous lymphocytes (SLVL) from CLL or hairy cell leukemia (HCL) that includes contacting a sample with a panel of antibodies that bind to CD antigens of CLL cells. Kurec teaches immunophenotypic classification of CLL (see page 46, Table 1). Thus, Moreau, Matutes or Kurec teaches a method that is the same as that claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Robbins (Robbins, B.A. et al., Blood, 82(4): 1277-1287, 1993) or Valet in view of Chang (U.S. Patent 4,591,570; issued May 27, 1986).

Claims 1-7 may be interpreted as drawn to methods where the antibodies that are used are associated with a solid support. Both Robbins and Valet fail to teach methods where the antibodies used in the methods are attached to solid supports. However, the use of antibodies that are attached to solid supports is well known in the art as evidenced by the disclosure of Chang, which discloses an immunoassay device comprising a pattern or array of antibodies coated spots on the surface of a support (see abstract). Thus, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to have modified the methods of Robbins or Valet to use antibodies attached to solid supports as disclosed in Chang. One would have been motivated to make such a modification because of the advantages of using antibodies arranged in arrays for tests that require the use of many different antibodies (see col. 1, line 32- col. 2, line 12).

7. Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terstappen (U.S. Patent 5,234,816; issued Aug. 1993), Moreau (Moreau, E.J. et al, Am. J. Clin. Pathol., 108: 378-382, 1997), Matutes (Matutes, E. et al., Blood, 83(6):1558-1562, 1994) or Kurec (Kurec, A.S. et al, British J. Haematology, 81: 45-51, 1992) in view of Chang (U.S. Patent 4,591,570; issued May 27, 1986).

Claims 1-3 and 7 may be interpreted as drawn to methods where the antibodies that are used are associated with a solid support. None of Terstappen, Moreau, Matutes or Kurec teaches methods where the antibodies used in the methods are attached to solid supports. However, the use of antibodies that are attached to solid supports is well known in the art as evidenced by the disclosure of Chang, which discloses an immunoassay device comprising a pattern or array of

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antibodies coated spots on the surface of a support (see abstract). Thus, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to have modified the methods of Terstappen, Moreau, Matutes or Kurec to use antibodies attached to solid supports as disclosed in Chang. One would have been motivated to make such a modification because of the advantages of using antibodies arranged in arrays for tests that require the use of many different antibodies (see col. 1, line 32- col. 2, line 12).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
March 6, 2003



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